Keeler

Cryomatic

Service Manual

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Appendix 1 – Probe Assembly Drawing

Safety Considerations

The system has been designed to comply with the following regulatory standards for Safety and Electromagnetic Compatibility:

- EN60601-1, UL60601-1 & CAN/CSA-C22.2 No 601.1
- EN60601-1-2

Although compliant with applicable EMC directives, this equipment may still be susceptible to excessive emissions and/or may interfere with other more sensitive material.

For your own safety and the safety of the equipment, always take the following precautions:

- Keep the console away from sources of liquids and do not spray with water.
- Do not use hypercarbonate or phenolic based cleaning solutions or disinfectants containing cationic surfactants (e.g. Dettox) to clean the probe.
- Ensure that the probe is clean and dry prior to storage.
- Observe the usual safety precautions, associated with the use of medical gases, at all times. Copies of these guidelines will be available from the gas supplier.
- Ensure the correct disposition of gas exhausted from the system so as to minimise the exposure to nitrous oxide. This is the responsibility of the user.
- Ensure that the probe is inspected by properly trained personnel once per annum for performance and safety checks and routine maintenance.
- Inspect the Cryo Tip for damage before every use. If there is any sign of damage the stem assembly must be replaced. Do not try to straighten a bent Cryo Tip.
- Do not try to re-shape a Cryo Tip.

SAFETY WARNINGS

Electrical equipment may be hazardous if misused. The equipment covers should only be removed by authorised technical personnel.

Do not use the system in the presence of flammable gases such as anaesthetic agents.

1. Introduction

About this Manual

This manual covers all aspects of servicing the Cryomatic Probe.

This manual is for use only by properly trained Keeler service engineers.

This manual assumes that the Cryomatic system has been correctly installed following the guidelines in the Cryomatic Operator Manual.

Scheduled Maintenance

The Cryomatic Probe should be inspected annually by Keeler trained personnel. This service will include:

a) Replace the Coupling Filters.
b) Replace the Hose Assembly.
c) Leak test to ITP010.
d) Final test to ITP009.

Modular Repairs

The probe has been designed in three modular sub assemblies, each can be removed and replaced:

a) The Connector Assembly
b) The Hose Assembly
c) The Stem Assembly

Other Repairs

In addition to the modular service approach there are several service procedures that require further disassembly:

a) Unblocking a Probe.
b) Repairing leaks.
c) Replacing the coupling filters.
d) Replacing the probe chip.
e) Reprogramming the probe.

Testing

Thorough testing following servicing is imperative to ensure maximum safety and performance to:

a) ITP010 - Leak Test
b) ITP009 - Final Test

2. Modular Repairs

Replacing the Stem Assembly

Remove the Stem Assembly.

a) Hold the handle and unscrew the front cap.
b) Remove the dowel pin.
c) Unscrew the handle from the probe body and pull back to expose the probe body.
d) Use a 10mm spanner on the flats of the probe body and tool KCP953 unscrew the stem nut.
e) Pull the stem assembly out of the probe body.

Fit the Stem Assembly.

a) Carefully press the stem assembly into the probe body, taking care not to damage the o-rings.
b) Screw the stem nut into the probe body, do not tighten.
c) Align the dowel hole and fit the dowel.
d) Use a 10mm spanner on the flats of the probe body and tool KC953 to screw the stem nut into the probe body.
e) Screw the front cap on to the probe body, whilst ensuring the dowel pin remains in place.

Test the Probe.

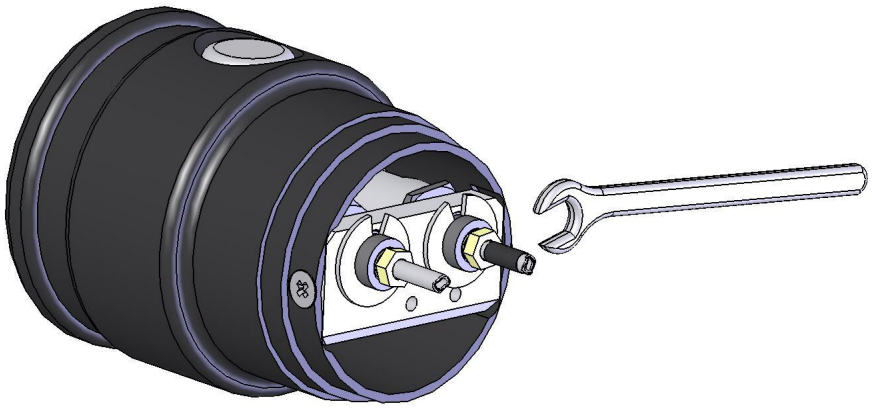
a) Leak test to ITP010.
b) Final test to ITP009.

Replacing the Hose Assembly

Remove the Stem Assembly as described in ‘replacing the stem assembly’

Remove the Coupling Assembly.

a) Unscrew the coupling shroud from the coupling body to expose the two hose connections.
b) Using 6mm spanner unscrew the retaining screw and pull the connection out of the coupling.
c) Discard the hoses.



Clean the Coupling ports.

a) Visually inspect the hose connector port and remove any visible debris.
b) Connect one port to the high pressure hose and gas through to blow out any debris.
c) Repeat with both ports.

Fit the new Hose Assembly.

a) Prior to fitting to the coupling check the hoses are not twisted along the entire length.
b) Push the hose connector into the receptacles on the coupling. Ensure the hose marked with black sleeve is fitted to the exhaust port.
c) Screw in the retaining screw and tighten using a 6mm spanner.
d) Repeat for both hoses.
e) Do not screw the coupling shroud in place until the probe has been leak tested to ITP010.

Clean the Hoses.

a) Connect one port to the high pressure hose and turn on the gas for 1 or 2 seconds to blow out any debris.
b) Repeat with both ports.

CAUTION: Ensure the hose is held firmly before applying pressure and that it is projected away from yourself or anyone else.

Fit the Stem Assembly as described in 'replacing the stem assembly'

Final Assembly and Test

a) Leak test to ITP010.
b) Screw the coupling shroud onto the coupling. Firmly grip the outer sleeve to prevent twisting.
c) Final test to ITP009.

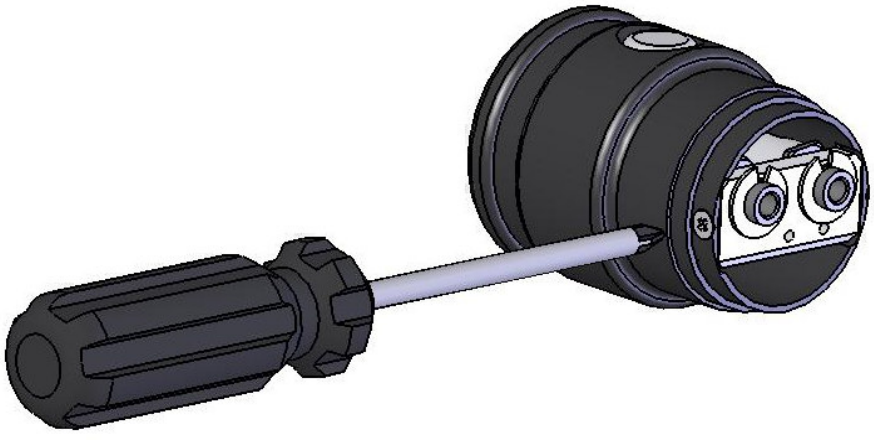
Replacing the Connector Assembly

Remove the Coupling Assembly.

d) Unscrew the coupling shroud from the coupling body to expose the two hose connections.
e) Using 6mm spanner unscrew the retaining screw and pull the connection out of the coupling.

Remove and replace the connector assembly.

a) Unscrew the two screws securing the connector assembly in the body.
b) Remove the connector assembly from the body.
c) Push the new connector assembly into the probe body. Ensure the alignment pins fit in the grooves in the probe body.
d) Screw in the two screws securing the connector assembly in the body.



Clean the Coupling ports.

d) Visually inspect the hose connector port and remove any visible debris.
e) Connect one port to the high pressure hose and gas through to blow out any debris.
f) Repeat with both ports.

Fit the Hose Assembly.

f) Prior to fitting to the coupling check the hoses are not twisted along the entire length.
g) Push the hose connector into the receptacles on the coupling. Ensure the hose marked with black sleeve is fitted to the exhaust port.
h) Screw in the retaining screw and tighten using a 6mm spanner.
i) Repeat for both hoses.
j) Do not screw the coupling shroud in place until the probe has been leak tested to ITP010.

Final Assembly and Test

d) Leak test to ITP010.
e) Screw the coupling shroud onto the coupling. Firmly grip the outer sleeve to prevent twisting.
f) Final test to ITP009.

3. Blocked Probe

Overview

On rare occasions the probe may become blocked due to debris or contaminants entering the system. The most likely source of contamination is from industrial grade gas or dirty gas cylinders which may contain particulate matter. Therefore to help minimise the chance of blocking it is important that medical grade gas is used.

It is also possible for debris to enter the system during service procedures that break into the gas line. Therefore it is advised to clean the hoses (as detailed in replacing the hose assembly) when these type of service procedures are carried out, even if the probe does not appear to be blocked.

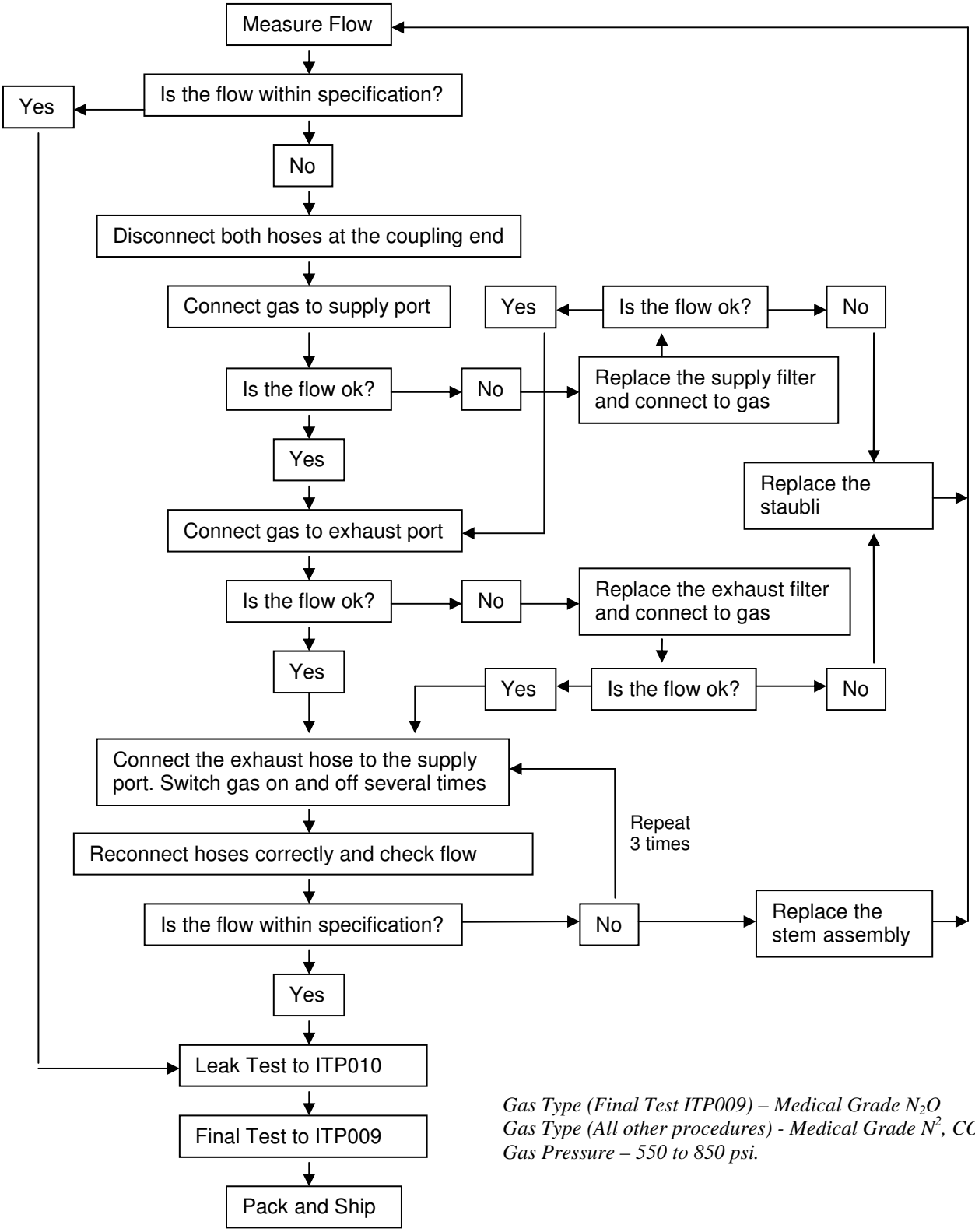
Repair

There are several places in a Probe where a block can occur as detailed below. However the most common area is the Stem Assembly.

a) Stem Assembly
b) Hose Connection.
c) Coupling Filter.

Refer to the fault diagnosis and repair tree to identify and repair the blockage.

Diagnosis and Repair Tree



Gas Type (Final Test ITP009) – Medical Grade N_2O
Gas Type (All other procedures) - Medical Grade N^2, CO^2, N_2O
Gas Pressure – 550 to 850 psi.

4. Repairing Leaks and Replacing Filters

Overview

Potential leak areas include the hose connection, coupling connector and stem assembly o rings. Leaks are most likely to occur following servicing of a probe. It is therefore important to leak test to ITP010 to identify the source of any leaks prior to final testing (ITP009).

Hose Connection Leak – Coupling

Remove the hose connection.

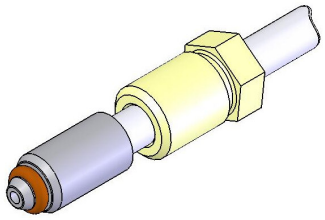
a) Unscrew the coupling shroud from the coupling body to expose the two hose connections.
b) Using 6mm spanner unscrew the leaking retaining screw and pull the connection out of the coupling.

Clean the coupling ports.

a) Visually inspect the hose connector port and remove any visible debris.
b) Connect the port to the high pressure hose and gas through to blow out any debris.

Fit a new o ring.

a) Discard the old o ring.
b) Fit a new o-ring.



Fit the hose connector.

a) Prior to fitting the hose connector ensure the hoses are not twisted along the entire length.
b) Push the hose connector into the hose connector port. The exhaust hose is indicated by a small length of black sleeve and must be fitted to the exhaust port.
c) Screw in the retaining screw and tighten.

Final Assembly and Test

a) Leak test to ITP010.
b) Screw the coupling shroud onto the coupling. Firmly grip the outer sleeve to prevent twisting.
c) Final test to ITP009.

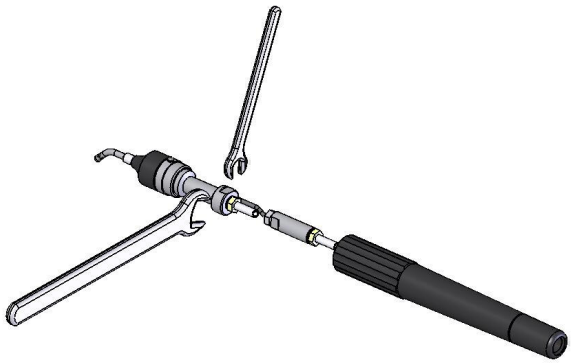
Hose Connection Leak – Probe

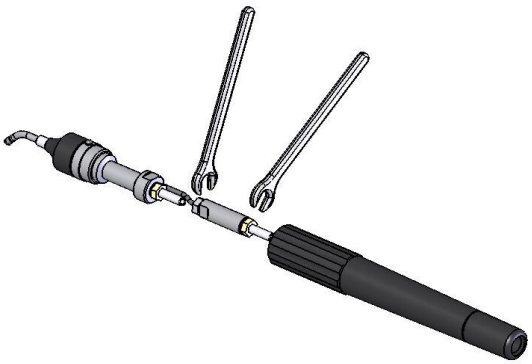
Expose the hose connections

a) Hold the probe body (exposed metal ring) and unscrew the handle. If the front cap unscrews first remove the cap to get a better grip on the probe body. If the front cap needs to be removed store the dowel pin as it will be reused.
b) Pull back the handle to expose the probe body. Confirm which hose connection is leaking by immersing probe in water whilst pressurised.

Disconnect the leaking hose connector.

a) Unscrew the retaining screw (17) from the receptacle (supply) using a 5mm spanner on the receptacle and a 6mm spanner on the retaining screw or:
b) Unscrew the retaining screw from the probe body (exhaust) using a 10mm spanner on the probe body and a 6mm spanner on the retaining screw.
c) Pull the hose connections out of the receptacle.





Fit a new o ring.

a) Discard the old o ring.
b) Visually inspect the hose connection port and remove any debris.
c) Fit a new o-ring.

Fit the hose connector.

a) Prior to fitting the hose connector ensure the hoses are not twisted along the entire length.
b) Push the hose connector into the hose connector port. The exhaust hose is indicated by a small length of black sleeve and must be fitted to the exhaust port.
c) Screw the retaining screw in and screw in – do not tighten.
d) Whilst holding the hose rotate the probe body approximately 90Deg to the right and then tighten.
e) Ensure the pip is in the correct orientation and adjust if necessary.

Final Assembly and Test

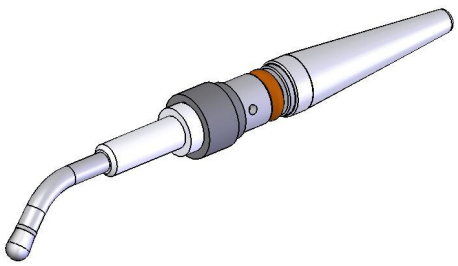
a) Leak test to ITP010.
b) Screw the handle onto the probe body. Rotate it 5 or 6 times counter clockwise prior to screwing on to allow for the twist of the outer sleeve.
c) Final test to ITP009.

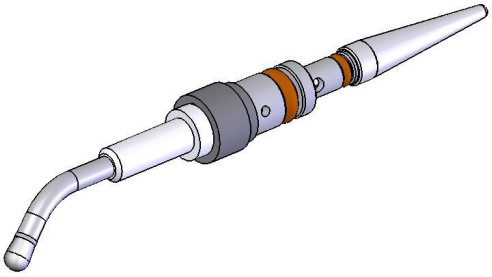
Replacing Stem Assembly O Rings

Remove the Stem Assembly as described in 'replacing the stem assembly'

Replace the O Rings

a) Remove both o rings taking care not to damage the sealing surfaces. A small pair of tweezers may be useful for this.
b) Using the large o ring bullet (KCP939) fit a new large o ring. Do not use any lubricant.
c) Using the small o ring bullet (KCP938) fit a new small o ring. Do use any lubricant.





Fit the Stem Assembly as described in 'replacing the stem assembly'

Test the Probe.

a) Leak test to ITP010.
b) Final test to ITP009.

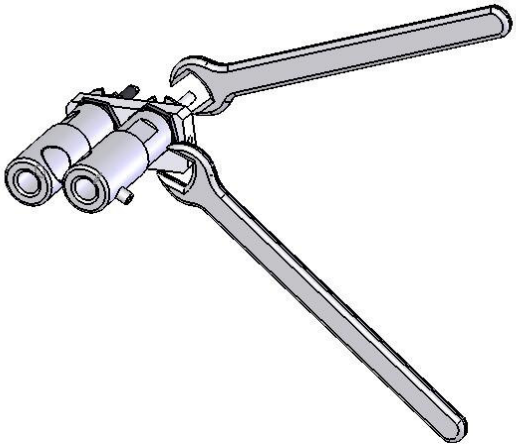
Replacing Connector Assembly O Rings and Filters

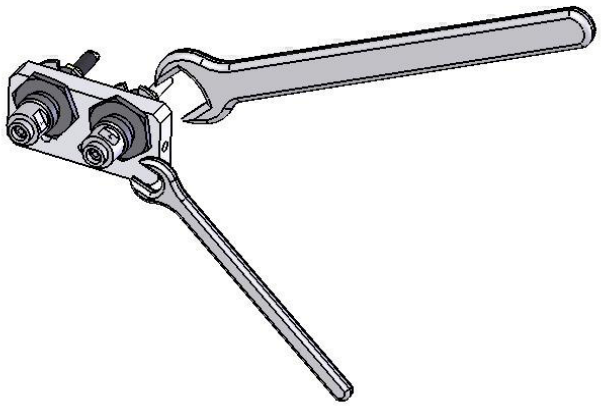
Remove the Connector Assembly

a) Unscrew the coupling shroud from the coupling body to expose the two screws.
b) Unscrew the two screws securing the connector assembly in the body.
c) Remove the coupling body from the connector assembly.

Disassemble Connector Assembly

a) Using a 13mm and 15mm spanner remove the Staubli connector from the hose connector. Take care to rotate the Stuabli connector and not the hose connector as this will damage the hoses.
b) Using a 6mm and 15mm spanner remove the filter holder from the hose connector, taking the same care not to rotate the hose connector.





Replace o rings and filter

a) Remove and discard the two o rings and fit with new ones.
b) Remove and discard the filter and fit a new one.

Reassemble Connector Assembly

a) Reassemble in the reverse order.
b) It may be necessary to loosen the hose connection in order to orientate the Staubli orientation pip.
c) Push the connector assembly into the probe body. Ensure the alignment pins fit in the grooves in the probe body.
d) Screw in the two screws securing the connector assembly in the body.

Final Assembly and Test

g) Leak test to ITP010.
h) Screw the coupling shroud onto the coupling. Firmly grip the outer sleeve to prevent twisting.
i) Final test to ITP009.

5. Probe Intelligence

Replacing the Probe Chip

Remove the chip

a) Unscrew the two screws holding the retaining plate in place.
b) Remove the retaining plate and chip.

Fitting the chip

a) Position the new chip in the slot such that the small side of the retaining plate will be positioned along the bottom edge.
b) Fit the retaining plate in position.
c) Retain in place with the two screws.

Reprogramming the Probe

To be completed

6. Spare Parts and Accessories

The following parts are available from the distributor.

Item No	*Description*	*Part Number*
1	Connector Assembly	KCP052
2	Hose Assembly	KCP053
3	Probe PCB Assembly	KCP054
4	Standard Retinal Stem Assembly	KCP201/1
5	Extended Retinal Stem Assembly	KCP201/2
6	Mid Reach Retinal Stem Assembly	KCP201/3
7	Glaucoma Stem Assembly	KCP201/4
8	Intravitreal Stem Assembly	KCP201/5
9	Cataract Stem Assembly	KCP201/6
10	Trichiasis Stem Assembly	KCP201/7
11	Contact Retainer	CSP210
12	Coupling Body	CSP211
13	Staubli Socket	CST256
14	M3x6 Pozi C'sk screw s/s	FAS039
15	M3x10 Pozi C'sk screw s/s	FAS040
16	S/S Dowel 1mm Dia x 4mm Lg Parallel	KCP211
17	Stainless Steel Wire 0.25mm	KCP212
18	006 Silicone O Ring	KCP213
19	606 Silicone O Ring	KCP214
20	Handle Front Cap	KCP301
21	Stem Nut	KCP308
22	Intravitreal Stem Spacer	KCP312/2
23	Sintered Filter	MCU219
24	1.5 x 1.5 Silicone O ring	MIS071
25	0051-16 Silicone O ring	

Tool List

- 5mm, 6mm, 10mm, 13mm, 15mm Spanner
- Medium Pozi Screwdriver
- Small Blade Screwdriver
- Tweezers
- Small Wire Cutters
- Small Pliers
- Plastic vernier or iceball gauge
- Flow Meter
- Console, mains lead, footswitch, gas and high pressure hose
- High pressure hose with coupling adaptor
- Small container of water for performance test
- Large container of water for leak testing
- Stem Nut Tool – KCP953
- Small O Ring Bullet – KCP938
- Large O Ring Bullet – KCP939

7. Troubleshooting Guide

The following table provides a troubleshooting guide for the Cryomatic system in the event of minor problems. If the problem is not cleared then the supplier must be contacted for further assistance. Prior to carrying out any service procedure refer to the troubleshooting guide in the user manual to eliminate any possible minor cause.

Problem	Possible Cause	Corrective Action
Low Flow Rate	Low freeze pressure.	Increase freeze pressure.
	Debris in probe.	Refer to diagnosis and repair tree and take appropriate action: - Reverse flush - Replace Stem Assembly - Replace Coupling filter and/or Staubli connector
	Moisture in probe.	Re-purge the probe.
High Flow Rate	High freeze pressure.	Reduce freeze pressure.
	Faulty stem assembly	Replace stem assembly.
Leak at probe end	Damaged hose connection o-ring.	Replace Hose Assembly (o-ring)
	Damaged o-ring on the stem assembly.	Replace o rings.
Leak at coupling end	Damaged hose connection o-ring.	Replace o-ring.
	Damaged coupling o rings.	Replace Coupling Assembly (o rings)
Damaged probe handle	Misuse.	Replace Hose Assembly. (handle parts)
Damaged Coupling body	Misuse.	Replace Coupling Assembly (body/shroud)
Console does not recognise probe	Faulty/Damaged Staubli connector.	Replace Coupling Assembly (Staubli)
	Faulty chip.	Replace Chip.
Coiled spring like hose	Hose has been tightly wound and autoclaved.	Replace Hose Assembly.
Orientation pip is misaligned	Incorrect assembly following service.	Adjust hose position in the handle.

*gas cylinders are deemed to be empty when the internal pressure is less than 350 PSI.

8. Warranty

The Cryomatic and its components are covered by warranty that they meet their performance standards and are free from any defects in materials or workmanship. Within 12 months from delivery by Keeler, the manufacturer shall at no charge to the customer, upon written notice from the customer, repair or replace any components which are defective in material or workmanship.

The customer agrees that it shall have no remedy in the event of any breach of the foregoing warranty other than as provided above. This warranty is exclusive and in lieu of all other warranties, expressed or implied, and all implied warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

The obligations of the manufacturer as set forth in this warranty are expressly conditioned on the following:-

(i) No alterations or repairs of any malfunction of the system shall be made to the system except by the manufacturer or his authorized representative, without the prior written approval of the manufacturer or his authorized representative (and in no case will the manufacturer assume responsibility for repairs or alterations made by those other than the manufacturer or his authorized representative).

And

(ii) The customer shall give notice to the manufacturer or their authorized representative of any malfunction of the system and shall not use the system in any surgical operation after they are aware of any malfunction.

(iii) The customer complies with manufacturer's recommended Preventative Maintenance (see Section 8) and can provide proof of such action.

9. Disposal

Ensure that this equipment is disposed of in accordance with local regulations. Please contact the supplier if in doubt.

10. Technical Data

Cryogenic System

Gas Specification:	Medical Grade Nitrous Oxide (N_2O) or Carbon Dioxide (CO_2) in non-syphon cylinders.
Operating Pressure Range:	3100 – 5860 kPa (450 – 850 PSI)
Maximum Pressure	8275 kPa (1200 PSI)
Freeze Control	Footswitch (press to freeze, release to defrost)

Electrical Ratings

Input Voltage Range:	110-240Vac (50/60Hz)
Power Rating:	100VA
Fuses:	T2AH 250V

Dimensions

Width:	305mm (12”)
Depth:	200mm (8”)
Height:	190mm (7.5”)
Weight:	2.5kg (6lbs)

Classification & Safety Standards

Complies with:	EN60601-1, UL60601-1 & CAN/CSA-C22.2 No 601.1
Equipment Classification:	Class 1, Type BF (Applied Part)
Mode of operation:	Continuous
Protection against ingress:	Console IPx0 Footswitch IP68

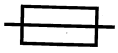
Environmental Conditions

	Storage	Operating
Temperature Range	-20°C to +50°C	+10°C to +40°C
Relative Humidity	10% to 80%	30% to 70%
Atmospheric Pressure	500hPa to 1060hPa	700hPa to 1060hPa

Symbols used on the equipment

All symbols used are in accordance with BS EN60417-2:1999 (Graphical Symbols for use on Equipment).

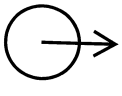
BF (Applied Part)


Fuse rating

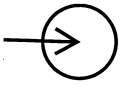
Refer to the User Manual

Footswitch connection

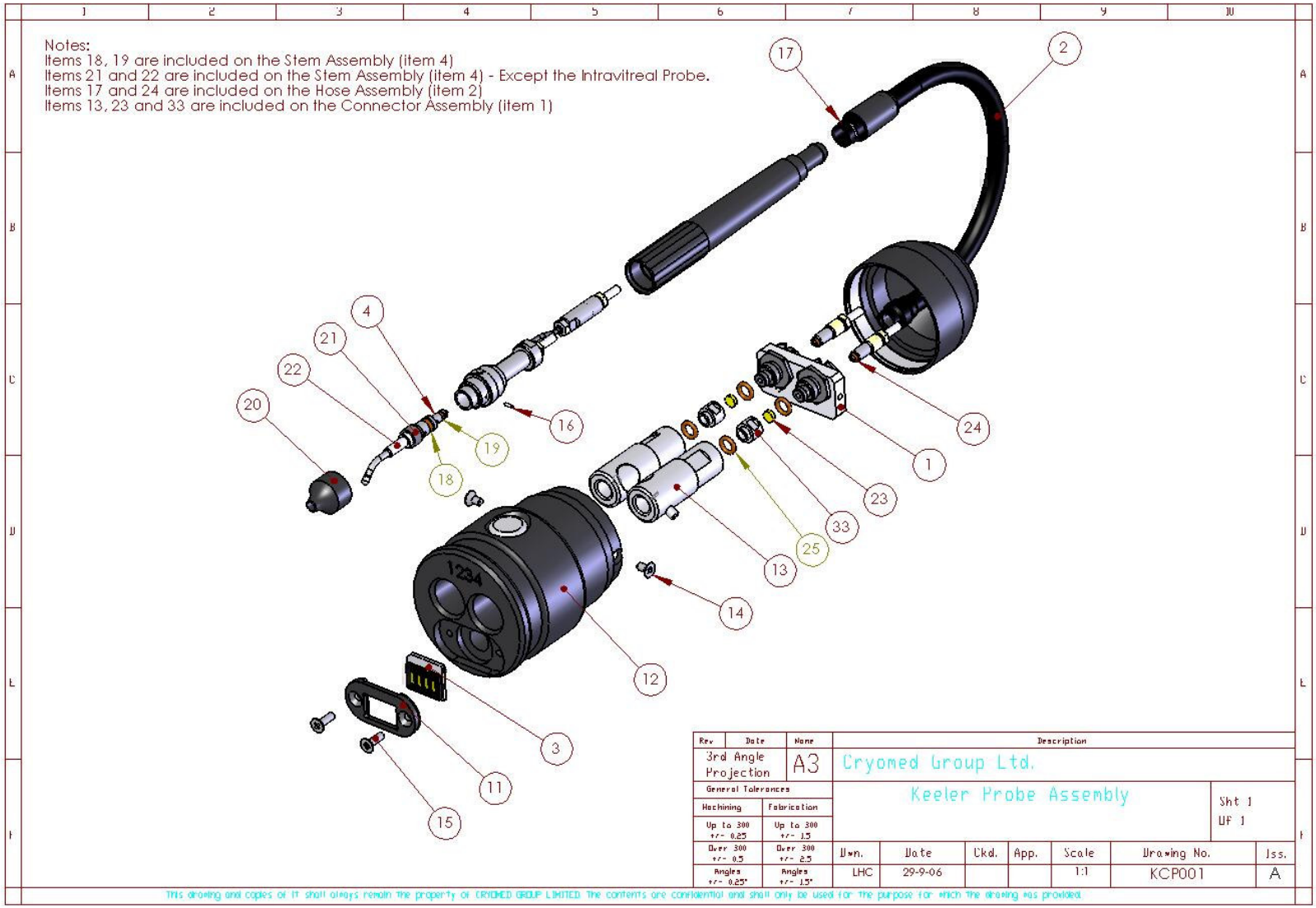
Dangerous voltages present inside the equipment


Exhaust connection

AC voltage input


Gas inlet connection

Appendix 1 – Probe Assembly



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